Clinical Trials Coordinator

Group	Science
Unit	Clinical Trials
Reports to	Program Manager, Clinical Trials Unit
Direct reports	Nil
Work location	HMRI Building, 1 Kookaburra Drive, New Lambton Heights
Employment status/type	Full-time (1.0 FTE)
Date (created or reviewed)	November 2021

Position purpose

The HMRI Clinical Trials Unit was established to provide clinical trial coordination as a service. The aim is to support our clients to prepare, design, secure approvals, recruit, execute and evaluate successful clinical trials.

The primary focus of the Clinical Trials Coordinator is to support the activities of a clinical trial or several clinical trials, including project management, administration and data entry support. The activities are determined by the size and type of trial and the needs of the client.

The incumbent works in accordance with the Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice ICH E6(R2) (2016) and the National Health and Medical Research Council (NHMRC) National Statement on Ethical Conduct in Human Research 2007 (updated 2018), and all other applicable Australian, state-specific and local regulations.

Key responsibilities

The key responsibilities of the role include, but are not limited to, the following:

1. Responsible for assisting with clinical trial activities and related operations at a participating site as contracted with the client, that may cover:

    - Implementing clinical trial practices, systems and procedures to best suit the needs of the clinical trial
    - Assisting with the preparation of trial documents for ethical review and managing the online submission of these documents for review and approval
    - Assisting with the preparation of site-specific participant-facing trial documents for Governance review and managing the online submission of these trial documents for review and approval / acknowledgment
    - Assisting with participant screening activities and attending participant study visits as required
    - Collecting and entering trial-specific data onto paper-based case report forms or into a clinical trial database
    - Tracking the financial aspects of the study e.g. site payments, and report with supporting documentation to the client

- Undertaking trial close-out including document archiving, ensuring study drug return/destruction and data system archiving after completion or termination of the trial

2. Responsible for assisting with clinical trial activities and related operations required by a Sponsor/CRO as contracted with the client, that may cover:

    - Preparing and maintaining trial associated documentation from commencement to close-out of the clinical trial

    - Collecting and reviewing essential documents from participating trial sites

    - Monitoring of participating sites to ensure data quality, accuracy, completeness and timeliness of data completion; complete and efficient resolution of data queries; adherence to the clinical trial protocol and adherence to ICH GCP and other guidelines relevant to the trial

    - Reporting on the progress of a trial including performance of participating sites in respect to recruitment, patient compliance, adverse events and general data quality and make recommendations to the client where appropriate

    - Undertake any other duties relevant and appropriate to this level as directed by the Associate Director, Clinical Trials Unit

HMRI expectations & legal compliance

- HMRI expects its people to contribute to the efficient and effective functioning of the organisation to meet HMRI and team strategic and operational objectives. This includes actively participating in the Individual Performance Plan and Review process, demonstrating appropriate and professional behaviour in accordance with HMRI's values and Code of Conduct, providing assistance to team members if required and undertaking other key responsibilities or activities as directed.

- All HMRI employees are expected to:

    - Make sound time management judgement in relation to prioritising work and meeting deadlines.

    - Perform their responsibilities in a manner which reflects and responds to continuous improvement.

    - Contribute to the effectiveness of the team.

    - Take responsibility for personal career development and training.

    - Read, understand and comply with all HMRI policies, procedures, and reasonable direction, as amended from time to time.

    - Ensure the reputation and integrity of HMRI is maintained at all times.

    - Maintain confidentiality at all times.

    - Attend HMRI-related functions, meetings, seminars, and/or training courses as directed, from time to time, by your supervisor.

    - Undertake risk management in accordance with HMRI's Risk Management Framework and actively support and participate in the risk management processes adopted by HMRI which include identifying, analysing and evaluating risk that may impact on HMRI.

    - Demonstrate understanding of the principles of anti-discrimination, equity, work health and

safety and other relevant legislation, and show the willingness and capacity to implement equal employment opportunity and work health and safety plans, policies and programs.

Other job-related information

Identification check

- The person appointed to this position will be required to complete a 100-point identification check and employment is subject to proof of the right to work in Australia.

Pre-existing injury

- The person appointed to this position will be required to disclose any pre-existing physical and/ or psychological injuries or disease that might be affected by employment in this position. This will assist HMRI in providing a safe work environment.

Occupational Assessment, Screening and Vaccination against Specific Diseases

- This is a Category A position. Please read and understand NSW Health policy directive PD2018_009. All new employees must agree to comply with the requirements outlined in this policy.

Additional hours

- The person appointed to this position may be required to undertake occasional work out of ordinary hours from time to time as may be required during the course of employment.

Essential position requirements

- Tertiary qualifications in Science, Health Science or Allied Health with at least one year subsequent relevant experience in clinical trial conduct; or an equivalent combination of relevant experience and/or education/training.

- Working knowledge of clinical research practices, including Good Clinical Practice (GCP) guidelines, the National Statement on Ethical Conduct in Human Research and governance principles

- Demonstrated attention to detail and accuracy, and ability to prioritise own work and maintain work standards with supervision

- Good interpersonal skills and proven ability to work as part of a team to achieve goals

- Strong computer and data entry skills, including databases in a windows environment, spreadsheets and word-processing. Working knowledge of project management and database software used in a clinical trials environment.

- Good written and verbal communication skills

- Demonstrated ability to work with discretion when handling sensitive information and ability to maintain confidentiality

I confirm that I have read this Position Description, understand its content and agree to work in accordance with the requirements of the position. I also understand that this document is intended to provide an outline of the key responsibilities of the position and that aspects of the document may change over time.

_____	_____	_____/_____/____
Employee Name	Employee Signature	Date

Note: A copy of this signed acceptance is to be placed on employee's personnel record and a copy provided to the employee.